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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,499

01/24/2005

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LABN:023US

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EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1797

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,499	Applicant(s) FLORIANO ET AL.	
	Examiner WILLIAM H. BEISNER	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-54, 69 and 81-94 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-54, 69 and 81-94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :9/12/2005; 3/20/2007; 11/21/2007.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements filed 9/12/2005; 3/20/2007; and 11/21/2007 have been considered and made of record.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 50-54, 69 and 81-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raspe (NL 1007489) in view of Hyldig-Nielsen (US 2002/0090626).

The reference of Raspe discloses a method of analyzing an analyte collected on a membrane that includes passing a fluid sample across a membrane wherein the fluid sample an analyte that is at least partially retained by the membrane (See the English language abstract). A visualization agent is added to the material collected on the membrane and the membrane is optically investigated using a microscope (See page 3, line 31, to page 4, line 2).

Claim 50 differs by reciting that the analyzing steps include imaging steps of generating a composite image using three different wavelengths of light and generating masks using two the wavelengths of light and subtracting the two masks from the composite image.

The reference of Hyldig-Nielsen discloses an image analysis method for distinguishing one type of bacteria from other present in a fluid sample that includes generating a composite image using three wavelengths of light (RGB) wherein the microorganism of interest is present in the green wavelength of light. Other microorganisms in the sample are present in the red and blue wavelengths of light. Using the different wavelengths of light the desired microorganism in the green wavelength of light can be determined (See paragraphs [0109]-[0115]).

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In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the image analysis method of the reference of Hyldig-Nielsen in the method of the primary reference when employing the system of the primary reference to detect for the presence of Salmonella bacteria in a sample liquid.

With respect to the specific steps of subtracting the blue and red masks from the composite image, the reference of Hyldig-Nielsen discloses that while the method discussed is based on manual analysis of computer generated digital images, the process can be automated using appropriate instrumentation and software (See paragraph [0117]).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to automate the manual process as suggested by the reference of Hyldig-Nielsen by using software to determine the presence of a desired analyte using the computer generated images. The use of masks to subtract the blue and red images from the composite image which would result in only a image container Salmonella would have been well within the purview of one having ordinary skill in the art.

With respect to claim 51, the method of the modified primary reference employs red, blue and green light.

With respect to claim 52, the method of the modified primary reference employs a computer for collecting the image data and generating the masks.

With respect to claim 53, if not inherent, one of ordinary skill in the art would be capable of modifying the method to determine the amount of analyte present in the sample.

With respect to claim 54, the images are collected using a digital detection device (See paragraph [0117]).

With respect to claim 69, the method resulting in the combination of the references of Raspe and Hyldig-Nielsen as discussed above with respect to claim 50 meets the limitations of claim 69.

With respect to claims 81 and 82, the membrane (13) is coupled to a membrane support (4) and body (1) (See Figures 1 and 2).

With respect to claim 83, subtracting background information from the detected image is well within the purview of one having ordinary skill in the art for the known and expected result of reducing the noise within the detection system. Also, cleaning the surface of the membrane would have been obvious for the known and expected result of allowing the device to be used for additional assays.

With respect to claims 84 and 92, the system of the modified primary reference would involve the use of a detector coupled to a programmable controller (See paragraph [0117]).

With respect to claims 85, 86 and 93, the system of the modified primary reference would include a step of adding a stain to the fluid wherein the stain emits light only in a specified portion of the visible spectrum (See paragraph [0109]-[0115] of Hyldig-Nielsen).

With respect to claims 87 and 88, if the generated masks are not inherently binary, it would have been obvious to one of ordinary skill in the art to employ binary masks since the system is generating digital images.

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With respect to claim 89, the stain for the Salmonella emits light only in the green portion of the visible spectrum. As discussed above with respect to claim 50, red and blue light would be subtracted as required in claim 89.

With respect to claims 90 and 91, the use of CCD cameras is conventional in the art of digital imaging and would have been obvious for the known and expected result of employing an art recognized means for capturing digital images as is required of the modified primary reference.

With respect to claim 94, the modified method discussed with respect to claim 50 involves the use of a plurality of wavelengths of light (red and blue).

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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7. Claims 50-54, 69 and 81-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-25 and 27-29 of copending Application No. 11/022,365. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 50-54, 69 and 81-94 are generic to all that is recited in claims 21-25 and 27-29 of copending Application No. 11/022,365. That is, claims 21-25 and 27-29 of copending Application No. 11/022,365 fall entirely within the scope of claims 50-54, 69 and 81-94 or, in other words, claims 50-54, 69 and 81-94 are anticipated by claims 21-25 and 27-29 of copending Application No. 11/022,365.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/William H. Beisner/
Primary Examiner
Art Unit 1797**

WHB